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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1165]

Draft Guidance for the Content of Premarket Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi." This guidance is neither final nor is it in effect at this time. This draft guidance describes the types of information that should be submitted in a premarket notification to support a decision of substantial equivalence for an extracorporeal shock wave lithotripter indicated for the fragmentation of kidney and ureteral calculi, including potential special controls. Although renal and ureteral extracorporeal shock wave lithotripters are currently classified into class III (premarket approval), elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify these devices to class II (special controls). It is anticipated that this draft guidance will become effective if/when a final rule regarding this reclassification has been issued.

DATES: Written comments concerning this draft guidance must be received by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Guidance for the Content of Premarket Notifications (510(k)s)

for Extracorporeal Shock Wave Lithotrippers Indicated for the Fragmentation of Kidney and Ureteral Calculi” to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818.

Written comments concerning this draft guidance must be submitted to the Dockets Management Branch, (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194.

SUPPLEMENTARY INFORMATION:

I. Background

Extracorporeal shock wave lithotrippers for the fragmentation of kidney and ureteral calculi are currently postamendments class III devices, requiring either an approved premarket approval (PMA) application or declared complete product development protocol (PDP) prior to commercial distribution in the United States. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify extracorporeal shock wave lithotrippers from class III into class II (special controls). To facilitate the proposed reclassification, FDA has prepared the draft guidance entitled “Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotrippers Indicated for the Fragmentation of Kidney and Ureteral Calculi.” This draft guidance describes the special controls that FDA is including in the proposed rule, and it also provides general guidance to industry on the content of premarket notifications for these devices.

A meeting of the Gastroenterology and Urology Devices Advisory Panel of the Medical Devices Advisory Committee was held on July 30, 1998, to seek its recommendations on this

proposed reclassification, including advice on special controls and the content of premarket notifications. The panel unanimously voted to reclassify the extracorporeal shock wave lithotripter for the fragmentation of renal and ureteral stones into class II. Comments from the panel have been incorporated into this draft guidance document.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the reclassification of extracorporeal shock wave lithotripters indicated for the fragmentation of kidney and ureteral calculi. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1226) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes "Guidance for the

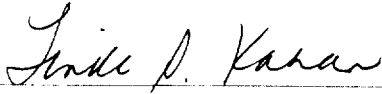
Content of Premarket Notifications (510k)s for Extracorporeal Shock Wave Lithotrippers Indicated for the Fragmentation of Kidney and Ureteral Calculi.” device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturers’ assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information.

IV. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that

individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/21/99
January 21, 1999



Linda S. Kahan
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

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